

Patients' Rights after Health Care Reform: Who Decides What Is Medically Necessary?

ABSTRACT

President Clinton's Health Security Act entitles individuals not to unlimited health care, but to a package of defined insurance benefits with specific exclusions and limitations. Like virtually all reform proposals, it would limit covered benefits to services that are medically necessary. If health reform is to control costs, not all medically necessary care can be covered. In the absence of a generally accepted definition of medical necessity, many services will not be guaranteed to all patients unless they are explicitly covered in the federal legislation or regulations. Without a federal definition of medical necessity or regulations listing covered services, health insurance plans will retain the primary authority to decide what is medically necessary for their patient subscribers. (*Am J Public Health*. 1994;84:1515-1520)

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Introduction

In December 1993, a jury in Riverside, Calif, found that Health Net, California's second largest health maintenance organization (HMO), wrongfully denied Nelene Fox insurance coverage for an autologous bone marrow transplant to treat her metastatic breast cancer.¹ The jury awarded Fox's estate \$12.1 million in compensatory damages for bad faith and reckless infliction of emotional distress and an unprecedented \$77 million in punitive damages. Fox's physicians had recommended the procedure, but Health Net decided it was experimental and unlikely to improve Fox's chances of survival because her cancer had metastasized. The jury, however, appears to have concluded that Health Net was interested only in saving money. The jury heard evidence that one physician withdrew his recommendation after speaking with Health Net's medical director, who could receive a bonus (20% of his salary) for saving money on expensive procedures, a compensation arrangement not uncommon among HMOs.² The jury may also have believed that Health Net, which had paid for at least two other transplants (one of which had resulted from a lawsuit), delayed its decision until Fox was too ill to qualify for transplantation. Fox underwent the procedure elsewhere in August 1992 after raising the \$212 000 in necessary funds, but she died in April 1993.³

Although the jury's award may be reduced or overturned on appeal, it offers a striking example of what is at stake in health care reform. The reform movement was catalyzed by the need to control costs, but few people are willing to accept limits on their own health care to save money. If the United States wants all Americans to have basic care at an

affordable cost, it will face Health Net's dilemma: whether to cover expensive services of debatable benefit.

Many cancer specialists recommend autologous bone marrow transplantation as a last hope for women with late-stage breast cancer even though there is still no definitive evidence that it prolongs survival in such cases. If, as some physicians suggest, up to one third of the 182 000 women diagnosed annually with breast cancer⁴ could be candidates for autologous bone marrow transplantation, the costs of treatment could exceed \$2 billion a year.⁵ Other expensive procedures have unknown or questionable benefits, but the absence of a cure for breast cancer—a widespread disease—has made autologous bone marrow transplantation the subject of dozens of lawsuits against health insurers, with mixed results.⁶ Blue Cross and Blue Shield are supporting clinical trials by the National Cancer Institute to determine the safety and effectiveness of autologous bone marrow transplantation in treating metastatic breast cancer,⁷ but those trials will not end the need to make difficult decisions. Medical science will continue to produce new procedures that raise the same questions: Are the procedures medically necessary and should they be covered?

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Note. This is the second of two articles on patients' rights after health care reform. The first article (which appeared in the August 1994 Journal) dealt with the ways in which patients' rights might and might not change under President Clinton's proposed Health Security Act.

Virtually all reform proposals contemplate limiting health insurance to medically necessary care. Yet there are few legal standards by which to judge what is medically necessary. Patients' rights to care after reform, therefore, will depend upon who decides what is medically necessary and what type of recourse is available to patients who believe they have been denied medically necessary care.

The Guaranteed Comprehensive Benefit Package

Like most other reform proposals, President Clinton's proposed Health Security Act, submitted to Congress in November 1993,⁸ does not guarantee universal access to unlimited health care. It combines mandatory health insurance with insurance reform.⁹ What individuals are entitled to under the terms of the act is "the comprehensive benefit package . . . through the applicable health plan in which the individual is enrolled."⁸(§1001) Patients' rights to health care would depend upon the terms of the health insurance contract (or federal statute, in the case of people electing to remain in federal statutory programs such as Medicare or the Department of Veterans Affairs health service). The contracts for health insurance are to be defined-benefit contracts. Care beyond that defined in the contracts would be the financial responsibility of the individual.

The comprehensive benefit package consists of a list of items and services that are described in general, categorical terms, such as "hospital inpatient services, services of physicians and other health care professionals, outpatient diagnostic and laboratory services."⁸(§1101) Some services are specifically excluded: cosmetic orthodontia and cosmetic surgery, in vitro fertilization, sex change surgery, investigational therapies, and most custodial care. The proposed act also restricts covered services in several ways. Clinical preventive services are limited to those listed in the act—a specific number of immunizations and tests (such as cholesterol tests, mammograms, and regular medical examinations) at specific ages (such as one influenza vaccination annually for adults over the age of 65). Hospice care, extended care, and home health care services are limited to a maximum number of days per year and then only for noncustodial purposes. Most routine vision and dental care is limited to children. Mental health and substance abuse services are

limited in both the nature of the service and the number of days per year allowed.

The most significant and comprehensive exclusion, however, is any "item or service that is not medically necessary or appropriate."⁸(§1141) This does not mean that patients are entitled to medically necessary care. Rather, they are eligible only for the benefits listed in the act, as long as the services are medically necessary and not otherwise excluded. Unfortunately, the act does not define "medically necessary." It does authorize a new federal National Health Board to determine by regulation that any item or service is not medically necessary or appropriate.⁸(§1141) But in the absence of any statutory standard, how will the National Health Board judge what services are medically necessary and appropriate?

What Is Medically Necessary?

The benefits and exclusions listed in the proposed act parallel those mentioned in most comprehensive private health insurance policies, with the addition of some preventive tests and immunizations. Indeed, the benefits are said to have been adapted from the insurance policies of a number of Fortune 500 companies. Private health insurance companies have relied on the concept of medical necessity to limit the services they will pay for in individual cases.^{6,10} Yet there is no universally applied definition of medical necessity available to serve as a national standard. Most insurers now have a medical review committee that assesses new medical procedures and technologies for the purpose of determining whether they are sufficiently accepted within the medical community to be covered as acceptable medical care. Still, such decisions are often made on a case-by-case basis with reference to the coverage terms of the insurance contract, not necessarily to conform to any comprehensive, overriding concept of medical necessity.

Several lower federal and state courts have discussed medical necessity in cases involving challenges to benefit denials. Most, however, have avoided defining the term. Often, courts have been asked to distinguish experimental therapy, which was excluded from coverage, from accepted or medically necessary treatment, which was covered.¹¹ State Medicaid programs may not deny services solely because of a patient's type of illness,¹² but they may limit services "based on such

criteria as medical necessity or utilization control procedures."^{13,14} Neither the federal Medicaid statute nor regulations define medical necessity. The federal court of appeals in *Rush v Parham*¹⁵ held that "a state [Medicaid program] may adopt a definition of medical necessity that places reasonable limits on a physician's discretion." One reasonable limit, said the court, is a ban on reimbursing "experimental forms of treatment, i.e., treatment not generally recognized as effective by the medical profession." A few courts have found that if "authoritative evidence" shows a therapy to be "safe and effective," even if it is novel or investigational, then it is not experimental and should be covered.^{16,17}

Courts have reached conflicting conclusions on how much reliance should be placed on a physician's determination of medical necessity, without specifying criteria for such a judgment. In holding that Medicaid should cover azidothymidine (AZT) treatment for patients with human immunodeficiency virus infection whose T-cell counts are above 200, a federal court of appeals relied on the widespread prescription of AZT by physicians to find it medically necessary, even though the Food and Drug Administration had not yet approved AZT for use with such patients.¹⁸ Earlier, that court had held that the decision whether a therapy is medically necessary rests with the patient's physician "and not with clerical personnel or government officials."¹⁹ This ruling contrasts with the more restricted role of physicians operating within Medicaid guidelines that other federal courts have endorsed.^{14,15}

Cases involving private insurers have also reached different results.¹⁰ Some courts have concluded that a private insurer cannot deny coverage solely because it disagrees with a physician's judgment of medical necessity.²⁰ Others have said that an insurer's interpretation of medical necessity must at least be consistent with community medical standards.²¹ Still others have found that whether a treatment is covered by insurance is a decision basic to the function of insurers, and that a physician's opinion, while highly probative, is not dispositive of the question of medical necessity.²²

One of the few definitions of medical necessity appears in a Florida statute that limits workers' compensation for medical care to medically necessary treatment:

"Medically necessary" means any service or supply used to identify or treat an illness or injury which is appropriate

to the patient's diagnosis, consistent with the location of service and with the level of care provided. The service should be widely accepted by the practicing peer group, should be based on scientific criteria, and should be determined to be reasonably safe. The service may not be of an experimental, investigative, or research nature, except in those instances in which prior approval . . . has been obtained.²³

Even this definition leaves a great deal open to interpretation. It does not require that medically necessary care be effective, and it permits payment for experimental services on a case-by-case basis. On the other hand, the fact that a service is not experimental does not necessarily mean that it is medically necessary.

In *Doe v Bolton*, the United States Supreme Court found that whether an abortion was necessary was a professional judgment to be exercised "in light of all 'factors—physical, emotional, psychological, familial, and the woman's age—relevant to the well-being of the patient.'"²⁴ In that case, the Court upheld a Georgia statute that banned abortions that physicians had determined to be unnecessary. Four years later, in a case challenging the Pennsylvania Medicaid program's refusal to fund nontherapeutic abortions, the Court indicated in a footnote that Pennsylvania's definition of medical necessity was "broad enough to encompass the factors specified in *Bolton*."²⁵ Some courts have assumed that the Court thereby adopted the *Bolton* factors as a definition of medical necessity for the purposes of Medicaid.²⁶ This seems doubtful, however. What qualifies as a necessary abortion for purposes of avoiding criminal prosecution may be quite different from what qualifies as necessary for purposes of Medicaid coverage. In *Harris v McRae*,²⁷ the Court held that states were not obligated to fund abortions that were conceded to be medically necessary because the Hyde Amendment adopted by Congress limited federal Medicaid funding to abortions that threatened the mother's life. Thus, although the Supreme Court has not expressly attempted to define medically necessary care for Medicaid or insurance purposes, it has not required the states to fund medically necessary services that Congress excluded from coverage. Moreover, it has upheld a state Medicaid program's limitation of inpatient care to 14 days a year, rejecting a challenge claiming that the limit discriminated against disabled patients who need longer hospitalizations.²⁸

It may be quite sensible to limit the new comprehensive benefit package to medically necessary care, but it will be hard to agree on what medically necessary care is.²⁹ One initial problem may be deciding what counts as a disease for which medical care is warranted at all. Disease and illness are cultural as well as biological concepts.^{30–33} In the 19th century, for example, some people believed that a disease called "drapetomania" caused slaves to run away.³⁴ Today there are controversies over whether chronic fatigue syndrome is a disease at all and how to diagnose Lyme disease.^{35,36} The difficulty of defining mental illness³⁷ may have contributed to the exclusion of many mental health services from coverage. The elusive nature of disease and the need for treatment make it difficult to find a single concept that is both comprehensive and specific enough to use as a standard for decision making, especially in a health care system serving people from many different cultural and ethnic backgrounds.

It is sometimes suggested that medical care is necessary when it restores a loss of function or remedies an abnormality.³⁸ But how do we distinguish between normal and abnormal? Should we measure against average human experience or an ideal standard of human capacity? The average may be what we want to overcome, but the ideal may be either unaffordable or unachievable.

The comprehensive benefit package described in the proposed act excludes cosmetic surgery, presumably because it is not necessary to treat disease or restore function. It also excludes in vitro fertilization services that treat the "disease" or condition of infertility. Perhaps infertility could be considered within the normal range of human conditions that do not require treatment. More likely, in vitro fertilization is excluded because it is believed to be insufficiently effective or too expensive. Sex change surgery might be excluded because gender dysphoria is not considered a medical condition requiring treatment, because the surgery is more expensive than psychotherapy, or because politicians do not like transsexual patients. In the absence of any explicit definition of what qualifies as medically necessary, the rationale for benefit exclusions remains speculative. This makes it difficult to predict what is or should be covered in the comprehensive benefit package.

The Health Plan's Role in Determining Medical Necessity

Given the difficulty of defining medically necessary care, whoever has authority to make decisions about what is covered by the comprehensive benefit package will control the care patients receive. The proposed National Health Board is to issue regulations concerning coverage, including new benefits and exclusions. But neither the Congress nor the National Health Board can be expected to list every product and service available and the circumstances in which it should be considered medically necessary. The state of Oregon discovered that such a listing was practically impossible when it ranked conditions and treatments for the purposes of its experiment with Medicaid. The treatment listed for 51% of 709 conditions was simply "medical therapy" or "medical and surgical treatment."³⁹ Most services cannot be classified dichotomously as either medically necessary or not necessary. Their utility and effectiveness often depend upon the medical condition of the patient they are intended to protect or treat. Even if some services can be correlated with particular conditions and appropriately classified, the majority are likely to remain uncategorized.

By default or by design, therefore, decisions about what counts as medically necessary care will be made, in the first instance, by individual health plans. Just as insurers do today, health plans may specify what is and is not covered as medically necessary care in the insurance contract, make decisions on a case-by-case basis, or both. Although all health plans will be required to offer the comprehensive benefit package, they will have considerable leeway to make plausible choices about what is medically necessary. (Variations in health plan coverage may result if plans offer more than the guaranteed minimum benefits. Plans may also offer insurance packages that vary the amount of deductibles, copayments, and coinsurance.) Thus, for patients not remaining in the federal statutory programs, rights to health care will depend, as they do today, on the patient's health insurance contract and insurer.

There is a disadvantage to relying on health plans to make coverage decisions in a reformed health care system that is supposed to reduce costs. Health plans have an incentive to minimize the scope of benefits. With limitations on the amount

of premiums they receive, health plans are expected to try to keep expenditures to a minimum in order to operate within allowable revenues.⁴⁰ No one seriously believes that this can be done without reducing payments to providers and suppliers. Administrative efficiency, although it may reduce costs to some extent, cannot be expected to produce savings sufficient to cover all services wanted or even needed by patients. Since health plans will not be able to save money by refusing to insure high-risk patients or by charging them higher premiums, the only alternatives are to limit payments to health care providers or to deny benefits to subscribing patients.

The most effective way to limit benefits to patients is by calling services medically unnecessary, thereby excluding them from coverage. Health plans may be reluctant to rely on physicians to make decisions about medical necessity unless physicians share the same financial risk as the health plan. Those who are paid a capitation fee or who participate in another financial risk-sharing arrangement may share the health plan's incentive to limit services.⁴¹ In that case, there may be little difference between decisions made by the physician and those made by the plan.

Physicians and other providers who are paid on a fee-for-service basis have few incentives to reduce services unless the fee is too low to compensate for the work involved. (In this case, the physician is likely to stop dealing with the health plan.) Thus, health plans offering fee-for-service benefits may prefer to retain the authority, as many do today, to determine whether any service is medically necessary regardless of a physician's recommendation. Nothing in the proposed act prevents health plans from reserving the power to make binding decisions on questions unresolved by the statute or regulations.

Disputes over coverage are most likely to involve expensive treatment that is either investigational (experimental) or only marginally effective.⁴² (Disputes may also arise over relatively inexpensive procedures, such as certain diagnostic tests, that can be used in large populations. Health plans may have an incentive to exclude coverage of such tests because of the volume they may generate. Patients, however, may not pursue a challenge of a health plan's denial of payment for such tests if the price is affordable.) For example, the National Health Board will undoubtedly have to take a position on whether autologous bone marrow trans-

plantation is medically necessary for the purposes of the comprehensive benefit package. The proposed act does not require the National Health Board to accept an individual physician's judgment on the nature of autologous bone marrow transplantation or any other service. Given the National Cancer Institute's ongoing clinical trials, the National Health Board could reasonably conclude that autologous bone marrow transplantation remains experimental and exclude it as not medically necessary in cases of metastatic breast cancer. A decision by the National Health Board will be binding on all health plans and patients. The Board's regulations will provide national consistency in coverage, but that consistency may come at the price of excluding some services that at least some health plans cover today. Of course, a health plan is free to cover services that are not included in the comprehensive benefit package, but few are likely to do so unless such coverage attracts enough subscribers to more than pay for the expected number of procedures.

Remedies for Erroneous Decisions about Medical Necessity

Lawyers are fond of noting that a right is only as good as the remedy for its denial. This is an apt observation with respect to patients' rights to health care benefits. Given that there are likely to be disputes about what benefits are covered in the guaranteed benefit package and that health plans have incentives to deny patients benefits for medically necessary care, patients' rights to medically necessary care will not be secure without some way to correct erroneous decisions.

To this end, the proposed act creates an elaborate patient grievance mechanism.⁸(Title V, Subtitle C) Patients who are denied benefits are entitled to complain to their health plan, and they may appeal adverse decisions to a complaint review office in their health alliance and ultimately to the federal courts. Quite properly, in cases in which a bodily function or the patient's survival is threatened, a health plan must respond to the complaint within 24 hours. An expedited review of the health plan's decision is also required.

There is no question that patients need to be able to check on benefits coverage quickly, especially when they are unable to pay for the service themselves.

In some cases, delaying treatment until a health plan confirms coverage may seriously jeopardize a patient's health. On the other hand, finding out that a procedure is not covered *after* it has been performed may bankrupt the patient who must pay out of his or her own pocket. In most cases, therefore, patients will be encouraged to seek a decision on coverage before undergoing expensive treatment.

Although necessary, patient grievance mechanisms encourage detailed and often lengthy reviews of numerous individual patient care decisions. No matter how responsive and efficient the system, such reviews are likely to be time-consuming and costly. In addition, different health plans may come to different conclusions about the medical necessity of the same service. The General Accounting Office recently reported that fewer than 10% of physicians' claims for Medicare payment were reviewed by medical professionals; the rest were decided by clerical employees, most with no more than a high school education.⁴³ This practice increased the likelihood of inconsistent coverage decisions, both within plans and among insurers. Inconsistent decisions encourage appeals, and consistency is rarely achieved until one reaches the highest appellate level. How many cases will it take to achieve consensus on the coverage of a single medical service? Although one might claim that a particular decision is inconsistent with the Health Security Act, inconsistency will be difficult to identify in the absence of federal regulations categorizing specific services or a federal definition of medical necessity.

Is Medical Necessity Necessary?

These important review processes will be made necessary by the requirement that covered benefits be medically necessary. To operate profitably (or perhaps just to break even), health plans must limit their coverage to medically necessary services. To do this, they may either delegate the authority to decide what is medically necessary to physicians and other health care providers or retain that authority themselves. If the health plans choose to retain the authority, they must monitor the patient care decisions made by providers and patients, either prospectively or retrospectively. Patients who cannot afford insurance beyond the guaranteed minimum benefit package and their physicians will have an incentive

to characterize desired treatment as something that will fit the health plan's definition of necessary and covered, as has occurred in the past.⁴⁴ The more patients fear that coverage might be denied after treatment, the more likely they are to seek a decision before the fact. The more treatments are prereviewed, the more administratively cumbersome health care will become.

The alternative is to delegate decision-making authority to the physician caring for the patient under a fixed or defined budget. Health plans could simply place a cap on the fees paid to providers and leave it to the quality assurance system to review providers' performance. Medical necessity could remain a criterion for the comprehensive benefit package in the proposed act, but health plans would not have to define or monitor medical necessity. Instead, physicians would make treatment decisions on the basis of their own professional definitions of medical necessity. (Insurers should be able to refuse payment for outlier decisions, such as the decision to treat influenza with a liver transplant, but placing a cap on payments to physicians should avoid the need to review each individual claim for payment.) Insurers would be protected from financial risk because they would not pay physicians on the basis of whether a service was medically necessary, but rather would pay a fixed or maximum fee per patient or group of patients.

This approach does have limitations. Like health plans, physicians whose incomes were limited under contracts with insurers might abuse their authority, misrepresenting medically necessary care as unnecessary to the patient in order to avoid incurring additional costs.⁴¹ In other words, they might do precisely what patients fear that health plans will do: deny patients care for their own financial gain. However, physicians and other health care providers have a better basis for judging medical necessity than do health plans or insurance companies. They may feel bound by the recommendations or treatment standards of professional organizations, whereas health plans may be freer to emphasize contract language over external practice guidelines. Physicians also have professional ethical and legal obligations to recommend medically necessary care to their patients, whether or not they provide it themselves and regardless of the prospects for payment.⁴⁵ Moreover, patients are more likely to prevail upon their physicians to provide treat-

ment than they are to prevail over insurance companies.

A second limitation of this approach is that the proposed act does not create a patient grievance mechanism for physicians' decisions to deny treatment. Physicians who do not recommend medically necessary treatment are already subject to malpractice claims today and would remain so under the proposed Health Security Act, regardless of how health plans behave. The available evidence suggests that only a small proportion of patients injured as a result of medical negligence actually file claims and no more than half of these patients receive any compensation.^{46,47} The numbers might increase as more patients are added to the health care system, but there is no reason to expect that new patients would file claims at a rate higher than the rest of the population.⁴⁸⁻⁵⁰ If a new quality assurance system improves provider performance, there may be less occasion for malpractice claims. There may be a question of whether cost considerations should affect the standard of care to which a physician should be held in a malpractice action,^{51,52} but the same question arises with respect to health plans that deny coverage of benefits for reasons of cost alone. Physicians, however, are not legally required to provide care free of charge or to pretend that excluded benefits are covered by the comprehensive benefit package. Rather, they are bound to disclose reasonable medical alternatives to the patient, whether these alternatives are covered or not. Thus, malpractice actions, as unpleasant as they are, ask the right question: Was appropriate care recommended?

Conclusion

The Clinton administration's approach to health care reform relies on the concept of medical necessity to control costs by limiting insurance coverage. In the past, services have been covered by insurance when they have been found to be generally accepted by the medical profession. But if health care reform is to reduce rising costs, not all beneficial and effective services can be included in the comprehensive benefit package. A more objective and explicit standard of medical necessity is needed, one that can be used as a statutory definition for purposes of resolving questions (and disputes) about legal entitlement to benefits.

In the absence of such a definition, specific benefits will have to be listed in the Health Security Act or regulations as

either covered or excluded. Thus, choices about what care patients are entitled to would become political decisions like those surrounding state legislation mandating benefits for private health insurance policies. Like state legislatures, Congress and the National Health Board would undoubtedly be visited by various groups lobbying for coverage of particular therapies.

Yet, if the federal government fails to define the comprehensive benefit package clearly (or fails to enact reform legislation), health plans will retain the first-line authority to decide what is medically necessary and therefore what is covered. This situation is likely to entail extensive health plan oversight of patient care decisions and encourage challenges to denials of specific treatments. Where physicians, rather than insurers, retain primary responsibility for deciding what is medically necessary within a specified budget, however, the need for case-by-case decision making by health plans declines. When global limits are placed on the costs of health care covered by a national program, both physicians and patients remain free to seek the most appropriate care. Thus, a defined-budget approach is likely to be both more flexible and less cumbersome than a defined-benefit approach to determining coverage of care.

In any event, there will still be a need for consistency in the use of new technologies that drive up health care costs. Only a national body like the National Health Board could develop recommendations or regulations that would offer the uniformity necessary to a fair distribution of services. Everyone would know in advance whether specific services were covered or excluded, thereby avoiding much of the unpredictability and anxiety of last-minute, case-by-case decision making. Although a national body would be subject to lobbying, it would be forced to consider the trade-offs involved in deciding whether to cover or exclude specific treatments. Without such a national body and uniform regulations, health plans will remain the primary arbiters of medical necessity, as they are today, with all the inconsistency and challenges that situation implies. It would be a shame to create a new health care system that recreated the problems that prompted reform. If health care reform is to serve all Americans, the National Health Board must make responsible decisions about what is medically necessary. □

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